K020268

APR 2 5 2002

510(k) Summary

ISAAC 1.5 T MR System

Common/Classification Name: Magnetic Resonance Diagnostic Device
21 CFR 892.1170

CHI, Inc.
104-10, Mun-Ji-Dong
Yu-Seong-Gu, TaeJon
KOREA

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Contact: Henry Jang, Prepared: January 16, 2002

A. LEGALLY MARKETED PREDICATE DEVICES

The **CHI 1.5 T MR System** is substantially equivalent to the Siemens Magnetom Symphony. The applicant believes that the device now called the Symphony is the same as the Siemens Magnetom Project 047, cleared by FDA as K971684 on August 5, 1997.

In regard to the six receive-only specialty coils, they are substantially equivalent to the similar coils manufactured by USA Instruments. These were cleared for marketing under the following 510(k)s: K971246 (knee coil), K010946 (shoulder coil), K964531 (neck coil), K972205 (wrist coil), K982340, and K980157 (CTL coil).

B. DEVICE DESCRIPTION

The **ISAAC 1.5 T MR System** is a new clinical whole-body MR system, utilizing a superconducting magnet operating at 1.5 T. A variety of pulse sequences are available as described in **Section II**. The system is provided with transmit/receive head and body coils, along with several receive-only specialty coils. The system utilizes an actively shielded gradient coil.

In regard to safety, the system always operates in the Normal Operating Mode for static field level, dB/dt and SAR, according to the proposed revision of the IEC 601-2-33 standard. The acoustic noise is well within the 99 dBA limit specified in the IEC standard.

C. INTENDED USE

The ISAAC 1.5 T MR System is a 1.5 T whole-body magnetic resonance imaging (MRI) system intended for general diagnostic use. Sagittal, coronal and oblique planes may be imaged. MRI images produced by the ISAAC system reflect the spatial distribution of the density of hydrogen nuclei (protons), spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in determining an diagnosis.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **ISAAC 1.5 T MR System** is a medical device, and it has the same indications for use and target population as the legally marketed predicate device. The **ISAAC 1.5 T MR System** has the same technological characteristics as the predicate devices. A comparison of the descriptive characteristics may not be sufficiently precise to assure substantial equivalence, so for those characteristics, performance data are provided to assure equivalence. These data do, in fact, demonstrate equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the **ISAAC 1.5 T MR System** are the same as for the predicate device.

F. TESTING

Testing to the appropriate NEMA performance standards was carried out and reported in this 510(k).

G. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2002

Chi, Inc.
% T. Whit Athey, Ph.D.
CL McIntosh & Associates
12300 Twinbrook Parkway
Suite 230
ROCKVILLE MD 20852

Re: K020268
Trade/Device Name: ISAAC 1.5 T MR System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: January 25, 2002
Received: January 25, 2002

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K020268

Device Name: ISAAC 1.5 T MR System

Indications For Use:

The ISAAC 1.5 T MR System is a 1.5 T whole-body magnetic resonance imaging (MRI) system intended for general diagnostic use. Sagittal, coronal and oblique planes may be imaged. MRI images produced by the ISAAC system reflect the spatial distribution of the density of hydrogen nuclei (protons), spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in determining an diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020268